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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,044	01/30/2002	Brian Robert Walker	674543-2001.1	8989

7590 06/18/2002
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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/061,044

Applicant(s)

WALKER ET AL.

Examiner

Barbara P Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/029,535.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

First Office Action on the Merits

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of inhibiting reductase activity or reducing intracellular glucocorticoid concentration by administering an inhibitor of reductase activity of 11 β -HSD1. The present specification discloses carbenoxolone as the only exemplified compound encompassed by the instant invention. The specification is not descriptive of other compounds that would inhibit the reductase activity of 11 β HSD1 and, thus, does not convey to the ordinary artisan in the art that applicant at the time the application was filed had possession of any other compound(s) useful as an inhibitor of said enzyme.

4. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for carbenoxolone, does not reasonably provide enablement for any other inhibitor of the reductase activity of 11 β HSD1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims encompass all compounds that would inhibit the reductase activity of 11 β HSD1. The present specification lacks a structural description and/or description of other compounds encompassed by the claimed invention and, thus, does not enable the skilled artisan to make and use the claimed invention commensurate in scope with these claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14, 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 15 are drawn to methods of inhibiting reductase activity or reducing intracellular glucocorticoid concentration by administering an inhibitor of reductase activity of 11 β -HSD1. The present specification discloses carbenoxolone as the only exemplified compound encompassed by the instant invention and lacks a structural description and/or description of other compounds encompassed by the

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claimed invention. Therefore, the ordinary artisan in the art would be unable to determine other compounds encompassed by the claimed invention and, thus, the metes and bound of the instant claims.

Claim 15 is also indefinite because it does not recite how said inhibition is obtained.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart et al.

Stewart et al. teach (a) the enzyme complex 11 β -hydroxysteroid dehydrogenase consists of 11 β -dehydrogenase which converts cortisol to cortisone and 11 β -reductase which converts cortisone to cortisol; (b) that carbenoxolone inhibits both 11 β -dehydrogenase and 11 β -reductase and (c) carbenoxolone is used in the treatment of peptic ulceration (see page 501, Abstract; page 506, col. 2, lines 4-27). The method of use taught by the reference is encompassed by the instant claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al.

Stewart et al. teach (a) the enzyme complex 11 β -hydroxysteroid dehydrogenase consists of 11 β -dehydrogenase which converts cortisol to cortisone and 11 β -reductase which converts cortisone to cortisol; (b) that carbenoxolone inhibits both 11 β -dehydrogenase and 11 β -reductase and (c) carbenoxolone is used in the treatment of peptic ulceration (see page 501, Abstract; page 506, col. 2, lines 4-27).

The instant claims differ from the reference by reciting "in adipose tissue of the animal". However, the ordinary artisan in the art would have the reasonable expectation that administration of carbenoxolone would result in the inhibition of the reductase activity of 11 β -hydroxysteroid dehydrogenase in any tissue in the body wherein the enzyme is found and, thus, the glucocorticoid concentration would also be lowered in said tissues.

It is noted that the ordinary artisan in the art would know that glucocorticoid increases acid and pepsin secretion which causes ulceration in animals. Therefore, the skilled artisan based on the teachings of Stewart would have the reasonable

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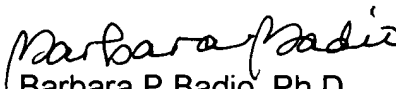
expectation that carbenoxolone decreases glucocorticoid levels by inhibition of the reductase activity of 11β -hydroxysteroid dehydrogenase.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB

June 14, 2002